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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/039,957	03/16/98	KORNBLITH	P 2509-970451

EXAMINER	
GITOMER, R	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/039,957	Applicant(s) Kornblith
	Examiner Ralph Gitomer	Group Art Unit 1623

☒ Responsive to communication(s) filed on *Sep 29, 1998* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-21* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-21* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *4*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

The IDS received 9/29/98 has been received and claims 1-21 are currently pending in this application. Applicants are requested to describe how the present specification and claims differ from those of parent application 08/679,056 and list any other related applications.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-21 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7 of copending Application No. 08/679,056. And claims 1-21 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-2 of copending Application No. 09/095,993. This

is a provisional double patenting rejection since the conflicting claims have not in fact been patented but have been allowed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-21 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Yen-Maguire, Stampfer, Morgan and Rotman.

Yen-Maguire (5,242,806) entitled "Method for Conducting the Cytotoxicity Assays on Tumor Cells" teaches in the abstract, assaying for the sensitivity of biopsied tumor cells to chemotherapeutic agents. In column 3 first full paragraph, measuring the responsiveness of multiple cell populations rather than single-cell suspensions. In column 3 lines 56-59, the requirement for single cell suspensions is eliminated. In column 10 lines 20-25, even if cells are seeded as aggregates, the cells will spread out.

Stampfer (4,423,145) entitled "Enhanced Growth Medium and Method for Culturing Human Mammary Epithelial Cells" teaches in column 3 under "Isolation of Epithelial Clumps," clumps of cells are obtained from a biopsy and then cultured. In column 6 last full paragraph, adriamycin sensitivity to specimens are determined with varying concentrations.

Morgan (5,270,172) entitled "Method to Predict Tumor Response to Therapy" teaches in column 5 Example 1, cancer tissue obtained is minced into fragments and cultured. In column 13 last full paragraph, chemotherapeutic drugs and doses are assayed.

Rotman (4,937,187) entitled "Methods for Separating Malignant Cells From Clinical Specimens" teaches in column 8 in the claims generally and claim 19 specifically, forming clumps of cells from tumor biopsies, establishing a cell culture, exposing the cell culture to a therapeutic agent and determining the sensitivity of the cells to the agent.

It would appear the inventive step is to not disaggregate a biopsy specimen into individual cells before plating but to plate clumps of cells prior to determining chemotherapeutic sensitivity. However, this is not claimed as the present claims are written in open-ended "comprising" terminology which does not exclude disaggregating the specimen and "multicellular particulates" does not define a size of specimen.

Claims 10 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 10 is directed to a wound healing agent and claim 17 is directed to a gene therapy agent.

The specification as originally filed does not enable one of skill in this art to make and use the presently claimed invention as directed to wound healing and gene therapy agents.

Claims 13-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for for specific markers or factors, does not reasonably provide enablement for any marker or factor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In claim 13 and all occurrences, the terms "soluble factors", in claim 14 "cellular markers", in claim 15 "cellular factors", in claim 21 "biological response modifier" lack enablement as it would require one of ordinary skill in this art undue experimentation to determine which such factor, marker or modifier would work in the instant invention.

"Soluble factors" reads on air which is unlikely to work in the claimed invention.

"Cellular markers" reads on utilization of a nutrient which is unlikely to work in the claimed invention.

"Cellular factors" reads on cost of media which is unlikely to work in the claimed invention.

"Biological response modifier" reads on air which is unlikely to work in the claimed invention.

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large proportion of inoperative compounds claimed.
2. Amount of direction or guidance presented is insufficient to predict which substances encompassed by the claims would work.
3. Presence of working examples are only for specific substances and extension to other compounds has not been specifically taught or suggested.
4. The nature of the invention is complex and unpredictable.
5. State of the prior art indicates that most related substances are not effective for the claimed functions.
6. Level of predictability of the art is very unpredictable.
7. Breadth of the claims encompasses an innumerable number of compounds.
8. The level of one of ordinary skill in this art is variable.

In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

Claims 1-21 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 line 2 and all occurrences, "patient cells" is not understood in context as to what sort of cells are intended. In claim 1(a) line 2, "cells ascites" is not understood. In claim 1© "said cohesive" lacks antecedent basis. In claim 1(e) "one active agent" means that the agent is active which is confusing in view of the assay to determine activity. In claim 1(e), there is no determining or correlating step so it is not seen how an assessment takes place. Further, "assessment" is not a gerund and so is improper. In claim 1(e) line 3, "in said site" lacks definite antecedent basis. Claim 2 and all occurrences is confusing because it refers to step (a) but contains a step (a). The tenses in claim 2 and all related occurrences are inconsistent and there is no harvesting step presented. In claim 4 how the assessment takes place is indefinite and it is not seen how one could determine optimal sensitivity to a single agent in the presence of many agents. In claim 5 "said plurality of active agents" lacks antecedent basis. In claim 6 "the sensitivity assayed" lacks antecedent basis. In claim 6 "anti-cancer" sensitivity is not understood. In claim 7 how the dispenser is used is not set forth and trademarks in claims are improper. In claim 8 how the cells are prepared is not recited. In claim 11 "and/or" is in the alternative. In claim 11 "ameliorating agent" is not understood in context. I claim 13 "the step of assessment of sensitivity" lacks antecedent basis. In claim 13 "soluble factors" does not include soluble in

what nor a factor to what. In claim 15 "cellular factors" is not understood. Claim 16 is improper and incomplete where it is directed to identifying antigens but lacks any such step.

The title of the invention is not aptly descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following prior art pertinent to applicant's disclosure is made of record and not relied upon: Kornblith (5,728,541) is a parent patent. Morgan (5,270,172) teaches in column 5 lines 45-50, a cellular suspension is made by cutting the pieces into 0.1 mm fragments. Yen-Maguire (5,242,806) teaches cytotoxicity assays. Stampfer (4,423,145) teaches culturing cells. Andreotti (J Biolumin Chemilumin) teaches chemosensitivity assays. Alley (Cancer Res) teaches tumor cell drug sensitivity. Kaaijk (Br J of Cancer) teaches on page 188 column 1 tumors were dissected to 0.5 - 1 mm. Fulda (Eur J of Cancer) teaches In Vitro drug tests. Dietel (Eur J Cancer) teaches drug resistance in cell cultures. Gearey (WO 96/10742) teaches assessment of cell activity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm.

The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1234.

Ralph Gitomer
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